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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

ESPERION THERAPEUTICS, INC.,	)	
	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 24-_____
	)	
ALKEM LABORATORIES LTD.,	)	
	)	
Defendant.	)	
	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

1. This is an action for patent infringement by Esperion Therapeutics, Inc. (“Esperion”) under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendant Alkem Laboratories Ltd. (“Alkem”). This action arises out of Alkem’s submission of Abbreviated New Drug Application (“ANDA”) Nos. 219416 and 219421 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell generic versions of NEXLETOL<sup>®</sup> and NEXLIZET<sup>®</sup> prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 10,912,751, and 11,744,816.

## **PARTIES**

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

3. Upon information and belief, Defendant Alkem is a corporation organized and existing under the laws of India, having a place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, Maharashtra, India.

4. Upon information and belief, Alkem is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

5. Upon information and belief, Alkem directly or through its affiliates markets and sells drug products throughout the United States, including in New Jersey.

6. Upon information and belief, Alkem works on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

7. Upon information and belief, Alkem prepared and submitted ANDA No. 219416 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL<sup>®</sup> (the “Alkem NEXLETOL<sup>®</sup> ANDA Product”) prior to the expiration of U.S. Patent Nos. 11,760,714 and 11,613,511. Upon information and belief, Alkem developed the Alkem NEXLETOL<sup>®</sup> ANDA Product.

8. Upon information and belief, Alkem is seeking regulatory approval from the FDA to market and sell the Alkem NEXLETOL<sup>®</sup> ANDA Product throughout the United States, including in New Jersey.

9. Upon information and belief, Alkem intends to obtain approval for Alkem's ANDA No. 219416, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Alkem NEXLETOL<sup>®</sup> ANDA Product in the United States, including in New Jersey.

10. Upon information and belief, Alkem prepared and submitted ANDA No. 219421 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLIZET<sup>®</sup> (the "Alkem NEXLIZET<sup>®</sup> ANDA Product") prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 10,912,751, and 11,744,816.

11. Upon information and belief, Alkem developed the Alkem NEXLIZET<sup>®</sup> ANDA Product.

12. Upon information and belief, Alkem is seeking regulatory approval from the FDA to market and sell the Alkem NEXLIZET<sup>®</sup> ANDA Product throughout the United States, including in New Jersey.

13. Upon information and belief, Alkem intends to obtain approval for Alkem's ANDA No. 219421, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Alkem NEXLIZET<sup>®</sup> ANDA Product in the United States, including in New Jersey.

### **JURISDICTION AND VENUE**

14. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Alkem because, among other things, it has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219416 in New Jersey,

and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219416, Alkem, will make, use, import, sell, and/or offer for sale the Alkem NEXLETOL<sup>®</sup> ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 11,760,714 and 11,613,511.

16. This Court has personal jurisdiction over Alkem because, among other things, it has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219421 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219421, Alkem, will make, use, import, sell, and/or offer for sale the Alkem NEXLIZET<sup>®</sup> ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 10,912,751, and 11,744,816.

17. This Court also has personal jurisdiction over Alkem because, among other things, this action arises from Alkem's actions directed toward New Jersey, and because, upon information and belief, Alkem has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; (3) creating a presence in New Jersey through its registration with the New Jersey Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0400132325; (4) working in concert to develop and market pharmaceutical products, including in New Jersey, with its

subsidiary Ascend Laboratories LLC, a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 339 Jefferson Road Suite 101 Parsippany, NJ 07054 USA and registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0600158194 (see <https://www.ascendlaboratories.com/Home/Background> and <https://www.ascendlaboratories.com/Home/Facility> (last visited May 14, 2024)) and (5) working in concert to develop and market pharmaceutical products in New Jersey with its subsidiary Enzene Biosciences, Ltd. (see <https://www.choosenj.com/news/enzene-expanding-to-new-jersey/> (last visited May 14, 2024)). Alkem has, therefore, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being hailed into court here.

18. In addition, this Court has personal jurisdiction over Alkem because, among other things, upon information and belief, (1) Alkem filed its ANDAs for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of the Alkem NEXLETOL<sup>®</sup> ANDA Product and the Alkem NEXLIZET<sup>®</sup> ANDA Product in the United States, including in New Jersey, and (2) upon approval of Alkem's ANDAs, Alkem will market, distribute, offer for sale, sell, and/or import the Alkem NEXLETOL<sup>®</sup> ANDA Product and the Alkem NEXLIZET<sup>®</sup> ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Alkem ANDA Products in New Jersey. Upon information and belief, upon approval of Alkem's ANDAs, the Alkem NEXLETOL<sup>®</sup> ANDA Product and the Alkem NEXLIZET<sup>®</sup> ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of

which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

19. This Court also has personal jurisdiction over Alkem because Alkem regularly engages in patent litigation in this forum, and affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction including in *Axsome Malta Ltd. v. Alkem Laboratories, Ltd.*, C.A. No. 24-cv-04608 (D.N.J. filed Apr. 5, 2024); *GW Research Limited v. Teva Pharmaceuticals, Inc.*, C.A. No. 23-cv-03914 (D.N.J. filed Jul. 21 2023); and *Arbor Pharmaceuticals, LLC v. Alkem Laboratories Ltd.*, C.A. No. 22-cv-00143 (D.N.J. filed Jan. 11, 2022).

20. Based on the foregoing systematic and continuous contacts with New Jersey, Alkem is subject to specific personal jurisdiction in New Jersey.

21. Upon information and belief, Alkem's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Alkem denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court also has personal jurisdiction over Alkem pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Alkem is not subject to the general jurisdiction of the courts of any state, and based on its contacts with the United States as a whole.

22. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Alkem to litigate this action in this Court, and Alkem is subject to personal jurisdiction in New Jersey.

23. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

24. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, Alkem is a corporation organized under the laws of India, is

not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

25. Venue is also proper in this Court because, among other things, Alkem has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell the Alkem NEXLETOL<sup>®</sup> ANDA Product and the Alkem NEXLIZET<sup>®</sup> ANDA Product in New Jersey; and (2) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

#### **THE PATENTS-IN-SUIT**

26. U.S. Patent No. 11,760,714 (the “’714 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on September 19, 2023. A true and correct copy of the ’714 Patent is attached hereto as “Exhibit A.”

27. Esperion is the assignee of, and holds all rights, title and interest in the ’714 Patent.

28. The ’714 Patent currently expires on June 19, 2040.

29. U.S. Patent No. 11,613,511 (the “’511 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on March 28, 2023. A true and correct copy of the ’511 Patent is attached hereto as “Exhibit B.”

30. Esperion is the assignee of, and holds all rights, title and interest in the ’511 Patent.

31. The ’511 Patent currently expires on June 19, 2040.

32. U.S. Patent No. 10,912,751 (the “’751 Patent”), entitled “Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease,” was duly and legally issued on February 9, 2021. A true and correct copy of the ’751 Patent is attached hereto as “Exhibit C.”

33. Esperion is the assignee of, and holds all rights, title and interest in the '751 Patent.

34. The '751 Patent currently expires on March 14, 2036.

35. U.S. Patent No. 11,744,816 (the "'816 Patent"), entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease," was duly and legally issued on September 5, 2023. A true and correct copy of the '816 Patent is attached hereto as "Exhibit D."

36. Esperion is the assignee of, and holds all rights, title and interest in the '816 Patent.

37. The '816 Patent currently expires on March 14, 2036

38. All claims of the '714, '511, '751, and '816 Patents are valid, enforceable, and not expired.

#### **ESPERION'S NEXLETOL PRODUCT**

39. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL<sup>®</sup> and NEXLIZET<sup>®</sup>.

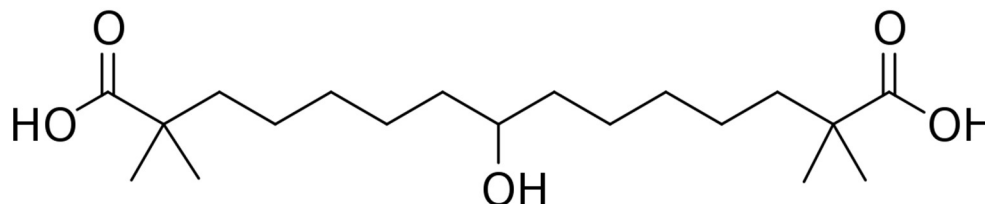
40. Esperion is the holder of New Drug Application ("NDA") No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name "NEXLETOL<sup>®</sup>." Esperion sells NEXLETOL<sup>®</sup> in the United States pursuant to NDA No. 211616.

41. NEXLETOL<sup>®</sup> (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible,



to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

42. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL<sup>®</sup>, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



43. The claims of the '714 and '511 Patents cover NEXLETOL<sup>®</sup>.

44. The '714 and '511 Patents have been listed in connection with NEXLETOL<sup>®</sup> in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."<sup>1</sup>

### **ESPERION'S NEXLIZET PRODUCT**

45. Esperion is the holder of NDA No. 211617, which was approved by the FDA on February 26, 2020, for the marketing and sale of a combined bempedoic acid and ezetimibe product in the United States under the trade name "NEXLIZET<sup>®</sup>." Esperion sells NEXLIZET<sup>®</sup> in the United States pursuant to NDA No. 211617.

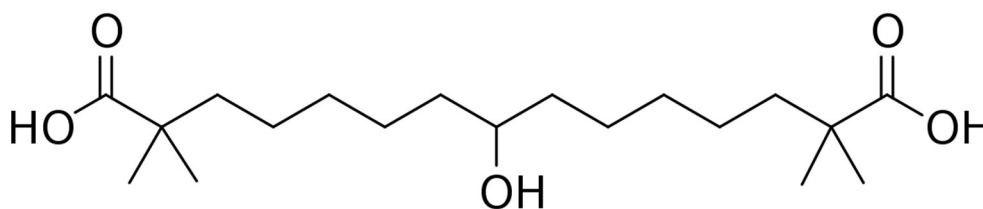
46. NEXLIZET<sup>®</sup> is a combination of bempedoic acid, an adenosine triphosphate citrate lyase (ACL) inhibitor, and ezetimibe, a dietary cholesterol absorption inhibitor, indicated as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)

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<sup>1</sup> The '816 Patent has also been listed in connection with NEXLETOL<sup>®</sup> in the Orange Book, but Alkem has not indicated in its NEXLETOL<sup>®</sup> Notice Letter (defined below) that it has submitted a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '816 Patent.

lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). The bempedoic acid component of NEXLIZET<sup>®</sup> is indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with (1) established cardiovascular disease (CVD), or (2) a high risk for a CVD event but without established CVD.

47. Bempedoic acid, one of the active pharmaceutical ingredients in NEXLIZET<sup>®</sup>, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



48. Ezetimibe, the other active pharmaceutical ingredients in NEXLIZET<sup>®</sup>, has the chemical name 1-(4-fluorophenyl)-3(R)-[3-(4-fluorophenyl)-3(S)-hydroxypropyl]-4(S)-(4-hydroxyphenyl)-2-azetidinone.

49. The claims of the '714, '511, '751, and '816 Patents cover NEXLIZET<sup>®</sup>.

50. The '714, '511, '751, and '816 Patents have been listed in connection with NEXLIZET<sup>®</sup> in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

#### **ALKEM'S NEXLETOL<sup>®</sup> ANDA PRODUCT**

51. By letter dated April 4, 2024, and received by Esperion via Federal Express on April 5, 2024 (the "NEXLETOL<sup>®</sup> Notice Letter"), Alkem notified Esperion that Alkem had submitted ANDA No. 219416 to the FDA for a generic version of NEXLETOL<sup>®</sup>.

52. The NEXLETOL<sup>®</sup> Notice Letter states that Alkem seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Alkem NEXLETOL<sup>®</sup> ANDA product before the expiration of the '714 and '511 Patents. Upon information and belief, Alkem intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Alkem NEXLETOL<sup>®</sup> ANDA product promptly upon receiving FDA approval to do so.

53. By submitting ANDA No. 219416, Alkem has represented to the FDA that the Alkem NEXLETOL<sup>®</sup> ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL<sup>®</sup> and is bioequivalent to NEXLETOL<sup>®</sup>.

54. In the NEXLETOL<sup>®</sup> Notice Letter, Alkem stated that ANDA No. 219416 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '714 and '511 Patents. Alkem also contended that the '714 and '511 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Alkem NEXLETOL<sup>®</sup> ANDA Product.

55. Upon information and belief, Alkem had knowledge of the '714 and '511 Patents when it submitted ANDA No. 219416 to the FDA.

56. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL<sup>®</sup> ANDA Product immediately and imminently upon approval of ANDA No. 219416.

57. Alkem's NEXLETOL<sup>®</sup> Notice Letter only identified invalidity positions with respect to the '714 and '511 Patents and included limited information about the Alkem NEXLETOL<sup>®</sup> ANDA Product. Alkem's Offer of Confidential Access permitted access only to limited, unspecified portions of Alkem's ANDAs on terms and conditions set by Alkem.

58. On or before April 29, 2024, Esperion sent Alkem a proposed revision of the Offer of Confidential Access to permit Esperion access to, among other things, the entirety of ANDA No. 219416.

59. Alkem has not provided a substantive response to Esperion's proposed revision of the Offer of Confidential Access and has not provided Esperion with any portions of its ANDA No. 219416.

60. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the NEXLETOL<sup>®</sup> Notice Letter.

**ALKEM'S NEXLIZET<sup>®</sup> ANDA PRODUCT**

61. By letter dated April 23, 2024, and received by Esperion via Federal Express on April 24, 2024 (the "NEXLIZET<sup>®</sup> Notice Letter"), Alkem notified Esperion that Alkem had submitted ANDA No. 219421 to the FDA for a generic version of NEXLIZET<sup>®</sup> (the Alkem NEXLIZET<sup>®</sup> ANDA Product").

62. The NEXLIZET<sup>®</sup> Notice Letter states that Alkem seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Alkem NEXLIZET<sup>®</sup> ANDA product before the expiration of the '714, '511, '751, and '816 Patents. Upon information and belief, Alkem intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Alkem NEXLIZET<sup>®</sup> ANDA product promptly upon receiving FDA approval to do so.

63. By submitting ANDA No. 219421, Alkem has represented to the FDA that the Alkem NEXLIZET<sup>®</sup> ANDA Product has the same active ingredient, dosage form, and strength as NEXLIZET<sup>®</sup> and is bioequivalent to NEXLIZET<sup>®</sup>.

64. In the NEXLIZET<sup>®</sup> Notice Letter, Alkem stated that ANDA No. 219421 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '714, '511, '751, and '816 Patents. Alkem also contended that the '714, '511, '751, and '816 Patents are

invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Alkem NEXLIZET® ANDA Product.

65. Upon information and belief, Alkem had knowledge of the '714, '511, '751, and '816 Patents when it submitted ANDA No. 219421 to the FDA.

66. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product immediately and imminently upon approval of ANDA No. 219421.

67. Alkem's NEXLIZET® Notice Letter only identified invalidity positions with respect to the '714, '511, '751, and '816 Patents and included limited information about the Alkem NEXLIZET® ANDA Product. Alkem's Offer of Confidential Access permitted access only to limited, unspecified portions of Alkem's ANDAs on terms and conditions set by Alkem.

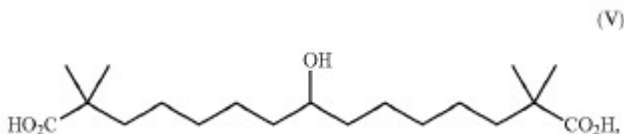
68. Alkem has not provided Esperion with any portions of its ANDA No. 219421.

69. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the NEXLIZET® Notice Letter.

**COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,760,714**  
**BY ALKEM'S NEXLETOL® ANDA PRODUCT**

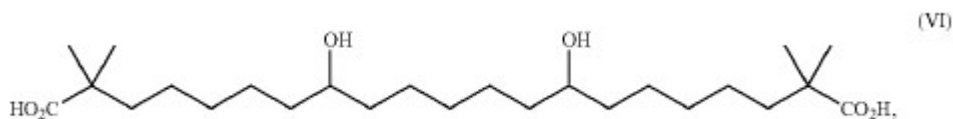
70. Esperion incorporates each of the preceding paragraphs 1 – 69 as if fully set forth herein.

71. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than

98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

72. Alkem's submission of ANDA No. 219416 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL<sup>®</sup> ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

73. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL<sup>®</sup> ANDA Product prior to expiration of the '714 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

74. Upon information and belief, upon FDA approval of ANDA No. 219416, Alkem intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL<sup>®</sup> ANDA Product, unless enjoined by the Court.

75. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's NEXLETOL<sup>®</sup> Notice Letter, Alkem has knowledge of the '714 Patent and knowledge that its Alkem NEXLETOL<sup>®</sup> ANDA Product will infringe the '714 Patent.

76. Upon information and belief, Alkem intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219416 is approved by marketing the Alkem NEXLETOL<sup>®</sup> ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

77. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219416 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLETOL<sup>®</sup> ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Alkem NEXLETOL<sup>®</sup> ANDA Product is not suitable for substantial noninfringing use.

78. Alkem's infringement is imminent because, among other things, Alkem has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL<sup>®</sup> ANDA Product before the expiration of the '714 Patent.

79. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

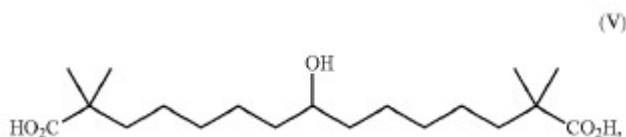
80. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL<sup>®</sup> ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

81. Unless Alkem is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

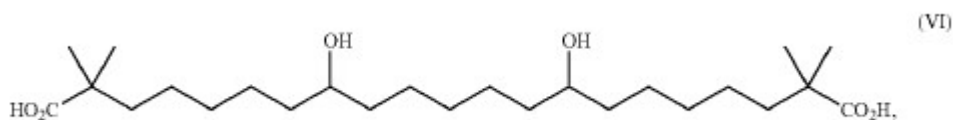
**COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,760,714**  
**BY ALKEM'S NEXLIZET<sup>®</sup> ANDA PRODUCT**

82. Esperion incorporates each of the preceding paragraphs 1 – 81 as if fully set forth herein.

83. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

84. Alkem's submission of ANDA No. 219421 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET<sup>®</sup> ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

85. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET<sup>®</sup> ANDA Product prior to expiration of the '714 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).



86. Upon information and belief, upon FDA approval of ANDA No. 219421, Alkem intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, unless enjoined by the Court.

87. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's NEXLIZET® Notice Letters, Alkem has knowledge of the '714 Patent and knowledge that its Alkem NEXLIZET® ANDA Product will infringe the '714 Patent.

88. Upon information and belief, Alkem intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219421 is approved by marketing the Alkem NEXLIZET® ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

89. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219421 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Alkem NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

90. Alkem's infringement is imminent because, among other things, Alkem has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product before the expiration of the '714 Patent.

91. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

92. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA

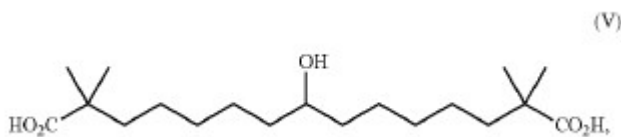
Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

93. Unless Alkem is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

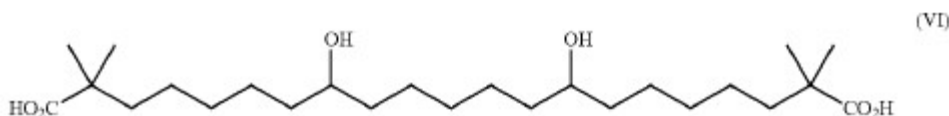
**COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,613,511**  
**BY ALKEM'S NEXLETOL® ANDA PRODUCT**

94. Esperion incorporates each of the preceding paragraphs 1 – 93 as if fully set forth herein.

95. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

96. Alkem's submission of ANDA No. 219416 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL<sup>®</sup> ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

97. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL<sup>®</sup> ANDA Product prior to expiration of the '511 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

98. Upon information and belief, upon FDA approval of ANDA No. 219416, Alkem intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL<sup>®</sup> ANDA Product, unless enjoined by the Court.

99. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's NEXLETOL<sup>®</sup> Notice Letters, Alkem has knowledge of the '511 Patent and knowledge that its Alkem NEXLETOL<sup>®</sup> ANDA Product will infringe the '511 Patent.

100. Upon information and belief, Alkem intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219416 is approved by marketing the Alkem NEXLETOL<sup>®</sup> ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

101. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219416 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLETOL<sup>®</sup>

ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Alkem NEXLETOL<sup>®</sup> ANDA Product is not suitable for substantial noninfringing use.

102. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

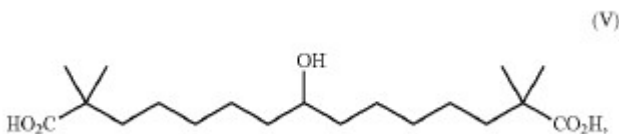
103. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL<sup>®</sup> ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

104. Unless Alkem is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

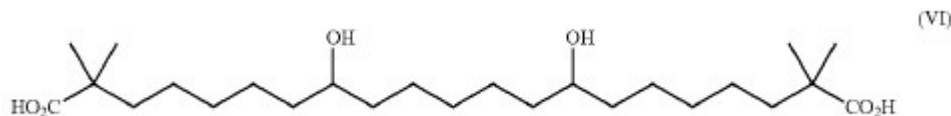
**COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 11,613,511**  
**BY ALKEM'S NEXLIZET<sup>®</sup> ANDA PRODUCT**

105. Esperion incorporates each of the preceding paragraphs 1 – 104 as if fully set forth herein.

106. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles ( $2\theta$ ):  $10.3\pm0.2$ ,  $10.4\pm0.2$ ,  $17.9\pm0.2$ ,  $18.8\pm0.2$ ,  $19.5\pm0.2$ , and  $20.7\pm0.2$ .

107. Alkem's submission of ANDA No. 219421 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET<sup>®</sup> ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

108. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET<sup>®</sup> ANDA Product prior to expiration of the '511 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

109. Upon information and belief, upon FDA approval of ANDA No. 219421, Alkem intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET<sup>®</sup> ANDA Product, unless enjoined by the Court.

110. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's NEXLIZET<sup>®</sup> Notice Letter, Alkem has knowledge of the '511 Patent and knowledge that its Alkem NEXLIZET<sup>®</sup> ANDA Product will infringe the '511 Patent.

111. Upon information and belief, Alkem intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No.

219421 is approved by marketing the Alkem NEXLIZET<sup>®</sup> ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

112. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219421 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLIZET<sup>®</sup> ANDA Products is especially made or adapted for use in infringing the '511 Patent, and that the Alkem NEXLIZET<sup>®</sup> ANDA Product is not suitable for substantial noninfringing use.

113. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

114. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET<sup>®</sup> ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

115. Unless Alkem is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

**COUNT V: INFRINGEMENT OF U.S. PATENT NO. 10,912,751**  
**BY ALKEM'S NEXLIZET<sup>®</sup> ANDA PRODUCT**

116. Esperion incorporates each of the preceding paragraphs 1 – 115 as if fully set forth herein.

117. Claim 1 of the '751 Patent claims a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2, 14, 14-tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

118. Alkem's submission of ANDA No. 219421 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET<sup>®</sup> ANDA Product before the expiration of the '751 Patent constituted an act of infringement of the claims of the '751 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

119. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET<sup>®</sup> ANDA Product prior to expiration of the '751 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '751 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

120. Upon information and belief, upon FDA approval of Alkem's ANDA No. 219421, Alkem will infringe at least claim 1 of the '751 Patent by making, using, offering to sell, and selling the Alkem ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '751 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

121. Upon information and belief, Alkem specifically intends to, and will, actively induce infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(b) when ANDA No. 219421 is approved by marketing the Alkem NEXLIZET<sup>®</sup> ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '751 Patent, unless enjoined by the Court.

122. Upon information and belief, Alkem's ANDA No. 219421 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Alkem NEXLIZET<sup>®</sup> ANDA Product.

123. Upon information and belief, upon FDA approval of ANDA No. 219421, Alkem intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET<sup>®</sup> ANDA Product, unless enjoined by the Court, and the Alkem NEXLIZET<sup>®</sup> ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

124. On information and belief, the proposed package insert will include a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2, 14, 14-tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

125. Upon information and belief, the use of the Alkem NEXLIZET<sup>®</sup> ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '751 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

126. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's Notice Letters, Alkem has knowledge of the '751 Patent and knowledge that its Alkem NEXLIZET<sup>®</sup> ANDA Product will infringe the '751 Patent.

127. On information and belief, Alkem is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Alkem NEXLIZET<sup>®</sup> ANDA Product at least according to Alkem's proposed package insert and, therefore, will directly infringe at least claim 1 of the '751 Patent.



128. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(c) when ANDA No. 219421 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '751 Patent, and that the Alkem NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

129. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '751 Patent.

130. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '751 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

131. Unless Alkem is enjoined from directly or indirectly infringing the '751 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

**COUNT VI: INFRINGEMENT OF U.S. PATENT NO. 11,744,816**  
**BY ALKEM'S NEXLIZET® ANDA PRODUCT**

132. Esperion incorporates each of the preceding paragraphs 1 – 131 as if fully set forth herein.

133. Claim 1 of the '816 Patent claims a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

134. Alkem's submission of ANDA No. 219421 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product before the expiration of the '816 Patent constituted an act of infringement of the

claims of the '816 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

135. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product prior to expiration of the '816 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '816 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

136. Upon information and belief, upon FDA approval of Alkem's ANDA No. 219421, Alkem will infringe at least claim 1 of the '816 Patent by making, using, offering to sell, and selling the Alkem NEXLIZET® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '816 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

137. Upon information and belief, Alkem specifically intends to, and will, actively induce infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(b) when ANDA No. 219421 is approved by marketing the Alkem NEXLIZET® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '816 Patent, unless enjoined by the Court.

138. Upon information and belief, Alkem's ANDA No. 219421 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Alkem NEXLIZET® ANDA Product.

139. Upon information and belief, upon FDA approval of ANDA No. 219421, Alkem intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, unless enjoined by the Court, and the Alkem NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other

third parties in the United States according to the directions and instructions in the proposed package insert.

140. On information and belief, the proposed package insert will include a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

141. Upon information and belief, the use of the Alkem NEXLIZET<sup>®</sup> ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '816 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

142. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's Notice Letters, Alkem has knowledge of the '816 Patent and knowledge that its Alkem NEXLIZET<sup>®</sup> ANDA Product will infringe the '816 Patent.

143. On information and belief, Alkem is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Alkem NEXLIZET<sup>®</sup> ANDA Product at least according to Alkem's proposed package insert and, therefore, will directly infringe at least claim 1 of the '816 Patent.

144. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(c) when ANDA No. 219421 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLIZET<sup>®</sup> ANDA Product is especially made or adapted for use in infringing the '816 Patent, and that the Alkem NEXLIZET<sup>®</sup> ANDA Product is not suitable for substantial noninfringing use.

145. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '816 Patent.

146. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '816 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

147. Unless Alkem is enjoined from directly or indirectly infringing the '816 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

#### **PRAYER FOR RELIEF**

WHEREFORE, Esperion asks that this Court grant the following relief:

148. A judgment that the claims of the '714 and '511 Patents are infringed by Alkem's submission of ANDA No. 219416 under 35 U.S.C. § 271(e)(2)(A);

149. A judgment that the claims of the '714, '511, '751, and '816 Patents are infringed by Alkem's submission of ANDA No. 219421 under 35 U.S.C. § 271(e)(2)(A);

150. A declaratory judgment that Alkem's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Alkem NEXLETOL® ANDA Product prior to the expiration of the '714 and '511 Patents, would infringe the '714 and '511 Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

151. A declaratory judgment that Alkem's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Alkem NEXLIZET® ANDA Product prior to the expiration of the '714, '511, '751, and '816 Patents, would infringe the

'714, '511, '751, and '816 Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

152. A judgment that the '714, '511, '751, and '816 Patents are not invalid or unenforceable;

153. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Alkem's ANDA No. 219416 shall not be earlier than the expiration of the '714 and '511 Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

154. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Alkem's ANDA No. 219421 shall not be earlier than the expiration of the '714, '511, '751, and '816 Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

155. An order permanently enjoining Alkem, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Alkem, from making, using, offering to sell, selling, or importing the Alkem NEXLETOL<sup>®</sup> ANDA Product until after the '714 and '511 Patents' expiration, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

156. An order permanently enjoining Alkem, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Alkem, from making, using, offering to sell, selling, or importing the Alkem NEXLIZET<sup>®</sup> ANDA Product until after the '714, '511, '751, and '816 Patents expiration, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

157. Damages or other monetary relief, including costs, fees, pre-judgment interest and post-judgment interest to Esperion if Alkem engages in commercial manufacture, use, offers to

sell, sale, or importation into the United States of the Alkem NEXLETOL<sup>®</sup> ANDA Product prior to the expiration of the '714 and '511 Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

158. Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Esperion if Alkem engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Alkem NEXLIZET<sup>®</sup> ANDA Product prior to the expiration of the '714, '511, '751, and '816 Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

159. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285; and

160. Such further and other relief as this Court deems proper and just.

Dated: May 17, 2024

/s/ Liza M. Walsh

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**LOCAL RULE 11.2 CERTIFICATION**

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following actions:

- *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc., et al.*, Civil Action No. 2:24-cv-05921-JXN-CLW
- *Esperion Therapeutics, Inc. v. Renata Limited*, Civil Action No. 2:24-cv-06017-JXN-CLW
- *Esperion Therapeutics, Inc. v. Accord Healthcare Inc., et al.*, Civil Action No. 2:24-cv-06224

Dated: May 17, 2024

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**LOCAL RULE 201.1 CERTIFICATION**

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: May 17, 2024

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